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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,176	07/18/2003	Elsa A.J.M. Goulmy	2183-6047US	4726

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,176	GOULMY ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Preliminary Amendment dated January 2, 2004 is acknowledged.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   1. Claims 1, 2, 4, and 5, drawn to a peptide and preparations consisting of VLXDDLLEA (SEQ ID NO:1), classified in class 514, subclass 2.

   2. Claims 1, 3, 4, and 6, drawn to a peptide and preparations consisting of KECVLXDDL (SEQ ID NO:3), classified in class 514, subclass 2.

   3. Claim 7 , drawn to a method of inducing tolerance using the peptide of SEQ ID NO:1, classified in class 424, subclass 185.1.

   4. Claim 7, drawn to a method of inducing tolerance using the peptide of SEQ ID NO:3, classified in class 424, subclass 185.1.

   5. Claim 7, drawn to a method of treating autoimmune disease using the peptide of SEQ ID NO:1, classified in class 424, subclass 184.1.

6. Claim 7, drawn to a method of treating autoimmune disease using the peptide of SEQ ID NO:3, classified in class 424, subclass 184.1.

7. Claim 8, drawn to a method of eliminating hematopoietic cells using the peptide of SEQ ID NO:1, classified in class 514, subclass 8.

8. Claim 8, drawn to a method of eliminating hematopoietic cells using the peptide of SEQ ID NO:3, classified in class 514, subclass 8.

9. Claim 9, drawn to an antagonistic analog of SEQ ID NO:1, classified in class 514, subclass 2.

10. Claim 9, drawn to an antagonistic analog of SEQ ID NO:3, classified in class 514, subclass 2.

11. Claim 10, drawn to a method of producing antibodies using the peptide of SEQ ID NO:1, classified in class 424, subclass 130.1.

12. Claim 10, drawn to a method of producing antibodies using the peptide of SEQ ID NO:3, classified in class 424, subclass 139.1.

13. Claim 10, drawn to a method of producing T cell receptors using the peptide of SEQ ID NO:1, classified in class 424, subclass 192.1.

14. Claim 10, drawn to a method of producing T cell receptors using the peptide of SEQ ID NO:3, classified in class 424, subclass 192.1.

15. Claim 10, drawn to a method of producing anti-idiotypic B cells using the peptide of SEQ ID NO:1, classified in class 424, subclass 131.1.

16. Claim 10, drawn to a method of producing anti-idiotypic B cells using the peptide of SEQ ID NO:3, classified in class 424, subclass 131.1.

17. Claim 10, drawn to a method of producing T cells using the peptide of SEQ ID NO:1, classified in class 424, subclass 93.71.

18. Claim 10, drawn to a method of producing T cells using the peptide of SEQ ID NO:3, classified in class 424, subclass 93.71.

19. Claim 10, drawn to a method of producing a mixture of products using the peptide of SEQ ID NO:1, classified in class 424, subclass 520.

20. Claim 10, drawn to a method of producing a mixture of products using the peptide of SEQ ID NO:3, classified in class 424, subclass 520.

21. Claim 11, drawn to antibodies produced using the peptide of SEQ ID NO:1, classified in class 530, subclass 387.1.

22. Claim 11, drawn to antibodies produced using the peptide of SEQ ID NO:3, classified in class 530, subclass 387.9.

23. Claim 11, drawn to T cell receptors produced using the peptide of SEQ ID NO:1, classified in class 530, subclass 350.

24. Claim 11, drawn to T cell receptors produced using the peptide of SEQ ID NO:3, classified in class 530, subclass 350.

25. Claim 11, drawn to anti-idiotypic B cells produced using the peptide of SEQ ID NO:1, classified in class 435, subclass 327.

26. Claim 11, drawn to anti-idiotypic B cells produced using the peptide of SEQ ID NO:3, classified in class 435, subclass 327.

27. Claim 11, drawn to T cells produced using the peptide of SEQ ID NO:1, classified in class 435, subclass 372.

28. Claim 11, drawn to T cells produced using the peptide of SEQ ID NO:3, classified in class 435, subclass 372.

29. Claim 11, drawn to a mixture of products produced using the peptide of SEQ ID NO:1, classified in class 435, subclass 325.

30. Claim 11, drawn to a mixture of products produced using the peptide of SEQ ID NO:3, classified in class 435, subclass 325.

31. Claims 12-19, drawn to a method of generating a CTL using a hematopoietic cell and a dendritic cell using the peptide of SEQ ID NO:1, classified in class 435, subclass 377.

32. Claims 12-19, drawn to a method of generating a CTL using a hematopoietic cell and a dendritic cell using the peptide of SEQ ID NO:3, classified in class 435, subclass 377.

33. Claims 20 and 21, drawn to a CTL generated by using a hematopoietic cell, a dendritic cell, and the peptide of SEQ ID NO:1, classified in class 435, subclass 331.

34. Claims 20 and 21, drawn to a CTL generated by using a hematopoietic cell, a dendritic cell, and the peptide of SEQ ID NO:3, classified in class 435, subclass 331.

35. Claims 22, 23, 38, 39, and 41, drawn to a method for eliminating or killing hematopoietic cells and/or tumors using SEQ ID NO:1, classified in class 424, subclass 277.1 .

36. Claims 22, 23, 38, 39, and 41, drawn to a method for eliminating or killing hematopoietic cells and/or tumors using SEQ ID NO:3, classified in class 424, subclass 277.1.

37. Claims 24 and 42, drawn to a method of determining the expression of the HA-1 mHag of SEQ ID NO:1 in the context of HLA class I on cell, classified in class 435, subclass 701.

38. Claims 24 and 42, drawn to a method of determining the expression of the HA-1 mHag of SEQ ID NO:3 in the context of HLA class I on cell, classified in class 435, subclass 7.1.

39. Claims 25 and 40, drawn to a method for marking hematopoietic and/or tumor cells with an HA-1 mHag of SEQ ID NO:1 binding molecule, classified in class 435, subclass 7.2.

40. Claims 25 and 40, drawn to a method for marking hematopoietic and/or tumor cells with an HA-1 mHag of SEQ ID NO:3 binding molecule, classified in class 435, subclass 7.2.

41. Claims 25 and 40, drawn to a method for marking hematopoietic and/or tumor cells using nucleic acids that encode SEQ ID NO:1, classified in class 435, subclass 6.

42. Claims 25 and 40, drawn to a method for marking hematopoietic and/or tumor cells using nucleic acids that encode SEQ ID NO:3, classified in class 435, subclass 6.

43. Claim 26, drawn to a non-hematopoietic tumor cell, classified in class 435, subclass 325.

44. Claims 27-29 and 43, drawn to a method of inhibiting the expansion of a tumor cell using SEQ ID NO:1, classified in class 435, subclass 375.

45. Claims 27-29 and 43, drawn to a method of inhibiting the expansion of a tumor cell using SEQ ID NO:3, classified in class 435, subclass 375.

46. Claim 30, drawn to a method of vaccinating individuals with the peptide of SEQ ID NO:1, classified in class 514, subclass 2.

47. Claim 30, drawn to a method of vaccinating individuals with the peptide of SEQ ID NO:3, classified in class 514, subclass 2.

48. Claim 31, drawn to a method of administering a non-hematopoietic tumor cell to individuals, classified in class 424, subclass 277.7.

49. Claim 32, drawn to a CTL isolated from an individual that had been administered a non-hematopoietic tumor cell, classified in class 424, subclass 93.21.

50. Claim 33, drawn to a method of for treating a disease by administering an antigen specific T cell, classified in class 424, subclass 93.1.

51. Claims 34, 37, and 47, drawn to a method of treating cancer using the HA-1 antigen of SEQ ID NO:1, classified in class 514, subclass 8.

52. Claims 34, 37, and 47, drawn to a method of treating cancer using the HA-1 antigen of SEQ ID NO:3, classified in class 514, subclass 8.

53. Claims 35 and 45, drawn to a method of producing HA-1 specific CTL in an HA-1 negative individual by administering the HA-1 antigen of SEQ ID NO:1, classified in class 514, subclass 8.

54. Claims 35 and 45, drawn to a method of producing HA-1 specific CTL in an HA-1 negative individual by administering the HA-1 antigen of SEQ ID NO:3, classified in class 424, subclass 93.21.

55. Claim 36, drawn to the method of claim 36 using the peptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

56. Claim 36, drawn to the method of claim 36 using the peptide of SEQ ID NO:3, classified in class 435, subclass 7.1.

57. Claim 44, drawn to the method of claim 44 using the peptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

58. Claim 44, drawn to the method of claim 44 using the peptide of SEQ ID NO:3, classified in class 435, subclass 7.1.

59. Claim 45, drawn to the method of generating CTL that recognize SEQ ID NO:1 by administering a tumor cell expressing SEQ ID NO:1 to an HA-1 mismatched individual, classified in class 424, subclass 277.1.

60. Claim 45, drawn to the method of generating CTL that recognize SEQ ID NO:3 by administering a tumor cell expressing SEQ ID NO:3 to an HA-1 mismatched individual, classified in class 424, subclass 277.1.

61. Claim 46, drawn to the method of claim 46 using the peptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

62. Claim 46, drawn to the method of claim 46 using the peptide of SEQ ID NO:3, classified in class 435, subclass 7.1.

63. Claim 48, drawn to the method of claim 48 using the peptide of SEQ ID NO:1, classified in class 435, subclass 7.1.

64. Claim 48, drawn to the method of claim 48 using the peptide of SEQ ID NO:3, classified in class 435, subclass 7.1.

Note that election of Groups 19, 20, 29, or 30 additionally requires Applicant to elect a defined combination of products (i.e. (antibodies and T cells), or (idiotypic B cells and antibodies), etc...). Election of Groups 19, 20, 29, or 30 without a positive identification of the mixture constituents will be held as a non-compliant response.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions (11-20 and 21-30), (31/32 and 33/34), and (48 and 49) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of Groups 21-30 could be obtained by the use of the entire HA-1 antigen rather than through the use of predefined epitopes of HA-1as in the methods of Groups 11-20. The CTL of Groups 33 and 34 could be made using macrophages as an antigen presenting cell rather than a dendritic cell as recited in Groups 31 and 32, while the CTL of Group 49 may be obtained by using hematopoietic tumor cells that express the desired antigen in the appropriate HLA molecule.

4. Inventions (1/2 and (3-8, 11-20, 31-32, 35-42, 44-47, and 51-64), (43 and 48), and (32/33/49 and 50) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the entire HA-1 molecule could substitute for the antigenic peptides in the recited methods, while the non-hematopoietic tumor cell of Group 43 could be used to study cancer in addition to its claimed use in generating CTL. The method of Group 50 can be performed with may products, such as those found in Groups 32, 33, and 49.

5. Inventions 1, 2, 9, 10, 21-30, 33, 34, 43, and 49 are different products. The peptides of SEQ ID NO:1 and SEQ ID NO:3 are distinct because they differ in structure, have different anchor residues at positions 2 and 9, are presented in the context of different HLA molecules (HLA A2.1 for SEQ ID NO:1 and HLA B60 for SEQ ID NO:3), and the identification of either one of these peptides would not anticipate nor render obvious the sequence, HLA restriction, and use of the other peptide. Since these peptides are distinct, reagents generated that are specific for either of these peptides are also distinct. Peptide analogs. antibodies, T cell receptors, anti-idiotypic B cells, T cells, and transfected tumor cells are structurally quite different, these differences giving rise to their unique functional properties that make one better suited than another for a

particular uses including therapeutic and diagnostic assays. Therefore they are patentably distinct.

6. Inventions 3-8, 11-20, 31-32, 35-42, 44-48, and 50-64 are different methods. As such they recite different process steps, require unique ingredients, and achieve divergent goals. The reagents and methods required to produce structurally distinct products and to treat patients using multiple products and techniques are all quite different, and a disclosure in the prior art of any one of the claimed methods would not necessarily anticipate nor render obvious any of the other recited methods. Therefore they are patentably distinct.

7. Inventions (1/2 and 50), (9/10 and (3-8, 11-20, 31-32, 35-42, 44-48, and 50-64)), (21-30 and (3-8, 31-32, 35-42, 44-48, and 50-64)), and (43/49 and (3-8, 11-20, 31-32, 35-42, 44-48, and 50-64) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the instant products cannot be directly used in or made by the recited method claims.

8. Because these inventions are distinct for the reasons given above, and the literature searches required for Groups 1-64 are not coextensive because art that reads on any one of the above Groups would not necessarily anticipate nor render obvious the

invention of any other Group, and Groups 1-64 have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct species of the claimed invention of Groups 1-42, 44-47, and 51-64. The distinct species are the identity of the amino acid denoted by the letter X in SEQ ID NO:1 and SEQ ID NO:3. Applicant is required to elect either histidine or arginine as the amino acid indicated by X in SEQ ID NO:1 or SEQ ID NO:3. These species are distinct because the structures of the resulting sequences are different.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims other than 2, 3, 5, and 6 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 4, 2005

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